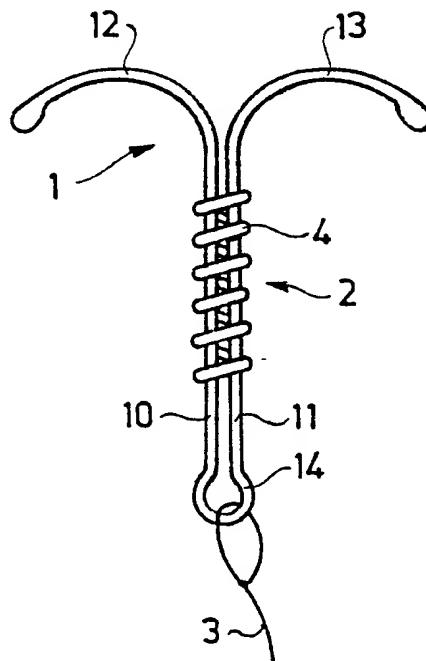




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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## (54) Title: INTRAUTERINE CONTRACEPTIVE DEVICE



## (57) Abstract

The present invention refers to an intrauterine contraceptive device comprising an active body (2) of a metallic substance of contraceptive activity, carrier means (1) for supporting the active body (2) in an intrauterine environment. The essence of this invention is that the active body (2) is made of at least two metals forming a plurality of galvanic cells in the intrauterine environment.

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1  
INTRAUTERINE CONTRACEPTIVE DEVICE

5

FIELD OF THE INVENTION

The present invention refers to an intrauterine contraceptive device comprising an active body made of a metallic substance of contraceptive activity and carrier means made of a biologically inert substance for supporting the active body in an intrauterine environment, wherein the carrier means are generally made of a plastic and connected with an indicator thread.

15

BACKGROUND OF THE INVENTION

The contraceptive effectiveness of some intrauterine devices has been known since many years. They have found application from the end of the sixties, when the appropriate plastics were prepared and investigated. Since that time the intrauterine devices have become applicable in a wide selection of different shapes, configurations and materials.

25

The process of the development of the intrauterine contraceptive devices can be shared into three periods. The first of them is marked by the application of the appropriate plastics (see e.g. US-PS 3.937.217), completed in the second period by a steroid-releasing substance. The third period is characterized in introducing copper for preparing the active body. The intrauterine devices based on copper comprise carrier means, generally made in T-shape from plastic (e.g. polyethylene) material, an active body made in form of a copper wire contacting the carrier means, further an indicator thread fixed on the carrier means.

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Mostly, the active body is a coil shaped element and the indicator thread is a flexible line made of plastic (e.g. polyamid).

The contraceptive effectiveness of the known intra-  
5 uterine devices comprising a copper wire is much higher  
than that of the devices prepared without any active  
substance. This recognition is based on different sys-  
tematicinvestigations. One of them is reported by I. Batár  
in the Orvosi Hetilap (Hungarian Medicine Weekly, 2237,  
10 129., 1988, in Hungarian). The effectiveness, rather to be  
called ineffectiveness of the intrauterine devices made  
with a copper wire (Type Multiload Cu 250) and those made  
without any active substance (so-called Szontágh's device  
produced in Hungary) were compared. The quantitative data  
15 were analysed by computing the so-called netto cumulative  
termination rates introduced by C. Tietze and S. Lewit  
(Stud. in Fam. Plann., 35, 4., 1973) and accepted in the  
international practice: the effectiveness is measured on  
the basis of the number of women conceiving within the  
20 period of one year among hundred having the intrauterine  
device. The corresponding data are: 2.2 for the Multiload  
Cu 250 device and 3.9 for the Szontágh's device, i.e. the  
first of the devices offers much higher contraceptive  
safety than the second one. In the article of I. Batár no  
25 analyse upon the merits of the technical features of the  
intrauterine devices can be found.

Inthe article mentioned above the clinical observa-  
tions continued over a period of about ten years are re-  
ported, too. The contraceptive intrauterine devices com-  
30 prising active bodies made with a copper wire were used by  
1446 women and the so-called cumulative pregnancy rate ap-  
peared to be 6.9. Because of 88 conceptions in the period  
observed the ineffectiveness was as high as 6.1 %. Other  
literature data (cited e.g. in Population Reports, Volume  
35 X,4., B103 to B135, 1985, Baltimore, USA) show similar in-

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effectiveness. The investigations carried out in some Latino-American countries gave the following characteristic data: the pregnancy rate was 5 % for the women using intrauterine devices including copper, 8 % in the women population taking oral contraceptives, 18 % in that applying mechanical contraceptives (condoms) and 40 % in the women population making no use of contraceptives.

In 1987 the proposal of S. G. Kaali, specializing in gynaecology in the Women's Medical Pavilion (Dobbs Ferry, New York, USA) became known for inactivating the spermatozoa in the uterus by the means of a weak electric current. The Kaali's contraceptive device hasn't been tested in human body, in any case, no such data were available prior to filing the present application; it consists of metallic electrodes arranged in the uterus and a battery connected with the electrodes.

The investigations have given a permanent evidence that the contraceptive effectiveness of the known intrauterine devices made with a copper wire forming an active body is as high as 94 to 95 % and this is a relatively low level when compared to 100 % assigned to the full safety. An improvement of the effectiveness is therefore highly desired.

A further drawback of the known intrauterine devices lies in that the copper material of the active body is slowly dissolving and consequently the active body during its presence in the human body fragmentates. The fragmented copper wire can harm thereby the tissues and has shortened life period. For avoiding the consequences of this drawback the U.S. Letters Patent 4 351 326 proposed to prepare the active body in form of a copper wire having a core consisted of a metal nobler than copper. The firm Schering AG (FRG) produces an intrauterine contraceptive device of this kind under the name NOVA T, wherein the core of the copper wire is made of silver. In this way the

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surface of the intrauterine device retains its required smoothness longer time than in the case of pure copper wires.

The contraceptive effect of the intrauterine devices comprising copper is supposed to be attributed even to copper. The dissolution process of copper, i.e. the speed of producing copper ions by the device is uneven, and therefore the known devices have a not stabilized influence on the physiological processes taking place in the human body (i.e. the enzyme processes, glycogen metabolism, absorption of estrogens, activity of the uterine muscles, changes in the composition of the fluids etc.), the influence on the mechanism of preventing the pregnancy, the implantation of the fertilized ovum.

15

#### SUMMARY OF THE INVENTION

The present invention is intended to creating an intrauterine contraceptive device of high contraceptive effectiveness reaching at least 99 % based on a metallic substance. The intrauterine device proposed by the invention should preserve its original shape during the whole period of application and ensure a uniform deliberation of the ions having contraceptive effect.

25

The invention is based on the recognition that the active body of the intrauterine device should be made of an appropriate metal composition containing at least two metals forming one with another a galvanic cell in the intrauterine environment.

30

Based on the recognition recited above an intrauterine contraceptive device has been created, which comprises an active body consisting of a metallic substance of contraceptive activity and carrier means made of a biologically inert substance for supporting the active body in an intrauterine environment, wherein according to the

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invention the active body is made of a metallic substance including at least two metals forming a plurality of local galvanic cells in the intrauterine environment. The active body is advantageously made at least partially of an alloy 5 of the at least two metals.

The plurality of the galvanic cells is advantageously consisted of a copper-gold or a copper-zinc-silver alloy. Of course, other alloys can be applied, too, and it 10 is especially desirable to prepare the active body from copper and at least one metal of higher electropositivity, when copper forms the anode of the galvanic cell and the other metal, e.g. gold or silver constitutes the cathode thereof. Some other metal composition are: nickel and gold, 15 copper, silver and zinc, silver and cadmium, silver and palladium.

The basic feature of the intrauterine device of the invention is that the active body includes a plurality of small, in most cases microscopic galvanic cells wherefrom the ions of the anode, generally the copper ions can be 20 dissolved with higher concentration than from the intrauterine devices of known designs.

The active body of the intrauterine contraceptive device proposed by the invention can preferably be made in the shape of a coil consisting of the mixture of more 25 metals (e.g. copper is completed with zinc and silver), wherein the mixture can constitute an alloy, too, if required. In this way more metals can be present in ionic form and in controlled amounts, whereby the potential difference between the electrodes of the galvanic cells is 30 stepwise increased and the effectiveness of the contraceptive activity possibly based on inactivating the spermatozoa is increased.

Another preferred embodiment of the active body is when prepared in tubular shape, wherein one or more tubular 35 elements are applied. In the case of more tubular elements

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they can be divided by ring shaped elements.

BRIEF DESCRIPTION OF THE DRAWINGS

5        Further advantages and features of the intrauterine contraceptive device proposed by the invention will be shown in more detail with reference to the accompanying drawings presenting by way of examples some preferred embodiments of the device. In the drawings

10      FIG. 1 is a schematic view of a proposed contraceptive device with coil shaped active body,  
FIG. 2 is the schematic view of an intrauterine contraceptive device including a tubular shaped active body made from an alloy sheet, and  
FIG. 3 is the schematic view of an intrauterine contraceptive device with an active body in form  
15      of two tubular and three ring form elements.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

20      As it is apparent from FIGS 1, 2 and 3 the proposed intrauterine contraceptive device of the invention consists of carrier means 1 made of plastic, an active body 2 of required activity exerted e.g. by inactivating spermatozoa in an intrauterine environment and an indicator thread  
25      3 connected to the carrier means 1 (FIGs. 1, 2 and 3.)

The carrier means 1 consist generally of an appropriate plastic which usually has no physiological activity in the intrauterine environment. The feature that the carrier means 1 are biological inert is, however, not a feature following from the contraceptive effectiveness of the active body 2 and if required, the carrier means 1 can be completed by further substances of appropriate activity. The carrier means 1 is generally a T-shaped, two arm element which can be arranged in the uterus of a woman and  
35      is intended to support the active body 2.

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The carrier means 1 generally consist of two stems 10 and 11 connected to one another in a loop 14 carrying the indicator thread 3 and continued in respective arms 12 and 13 (FIG. 1).

5       The active body 2 of the proposed intrauterine device is generally produced in form of a coil 4 wound around the two stems 10 and 11 of the carrier means 2 (FIG. 1). The coil 4 can be also a double helix prepared from a wire by the means of known mechanical technologies. The  
10 simple coil 4 or the double helix, i.e. a coil wound from another coil prepared from a wire offer high surface area.

Another possibility of shaping the active body 2 is shown in FIG. 2., wherein the active body 2 consists of a tube 5 surrounding the two stems 10 and 11 from the loop 14 up to the beginning of the arms 12 and 13. The tube 5 can be produced by forming a metallic sheet to a tubular element and closing, e.g. by welding the metallic sheet along the lines of connecting the edges of the sheet to one another.  
15

20       A yet further preferred possibility can be seen in FIG. 3., wherein an active body 2 is divided into more parts: the stems 10 and 11 are partly covered by tubular elements 7 and a ring 6 arranged therebetween. Further rings 8 are placed at the free ends of the respective arms  
25 12 and 13. This solution is especially advantageous when the active body 2 consists of sheet- and wire-like elements with inhomogenized surface layer including the at least two metals forming microscopic or small galvanic cells as required by the invention. The two or more metal composition  
30 is also a requirement against the coil 4 and the tube 5, made in whole volume or at least on the outer surface of at least two metals.

Generally, the active body 2 includes copper and at least one further metal of higher electropositivity, e.g.  
35 gold or silver. These metals can form either a mixture or

an alloy. A third and further metal can be applied, too, and in this way a series of galvanic cells of different voltages is applied. Other preferred selections for preparing the active body 2 are listed up in the examples given  
5 below, however, it is not intended to be limited by the examples.

In the intrauterine environment the proposed contraceptive device forms a plurality of galvanic cells with electrodes in the active body 2. The electrolyte is the  
10 biologic fluid of the uterus. If the active body is made of a given first metal, e.g. copper and a more noble metal, e.g. gold the rules of the electrochemical corrosion predict that the anodes are at the "isles" formed by the first metal, i.e. copper and the cathodes at the parts consisted  
15 of the nobler metal, i.e. gold. The dissolution process results in removing first metal from the active body 2 and the cathodes remain practically without change on their original places, their fragmentation can not be observed. In the galvanic cells the concentration of the first metal ions, i.e. the copper ions is higher than in the environment of the known intrauterine devices.  
20

Because of applying a mixture or alloy containing at least two metals the process of deliberating the ions ensuring the contraceptive activity of the proposed device  
25 becomes controlled, the cathodes or cathode isles ensure retaining the original shape of the active body 2 and the problems linked with the fragmentation of the active body 2 resulting in rough, splintered outer surface thereof in the known devices can be avoided. The composition of the mixture or alloy of the active body 2 can be selected in a wide range including more orders of magnitudes.  
30

The proposed intrauterine contraceptive devices operate in the following way: The small or microscopic galvanic cells created by the component metals of the active

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body 2 are capable not only of deliberating the required active ions in the intrauterine environment but also of generating an electric field. Therefore the contraceptive activity supposed to be based on chemical effects is intensively improved by the electric field. It is known that the spermatozoa have electric charge and this results in their migration to the cathodes and anodes of the galvanic cells, respectively, according to their electric charges. Thereby the inactivating process of the spermatozoa shows higher effectiveness than in the known devices.

A further advantage of the proposed intrauterine contraceptive devices lies in the fact that during the excitation accompanying the sexual intercourse, when the temperature of the human body exceeds the normal level, the intensity of deliberating ions in the galvanic cells increases what results in higher activity of the proposed intrauterine contraceptive device when this is especially required.

Further some examples will be shown:

20

#### EXAMPLE 1.

The active body 2 of the intrauterine device proposed by the invention is a coil 4 (FIG. 1.) consisting of 85 parts copper and 15 parts gold. The coil 4 is wound from a wire and surrounds the carrier means 1 made of polyethylene. The carrier means 1 are connected with a polyamide thread 3.

#### EXAMPLE 2.

The active body 2 of the intrauterine device proposed by the invention is a coil 4 (FIG. 1.) consisting of an alloy including 30 parts zinc and 70 parts copper. The coil 4 is wound from a wire and surrounds the carrier means 1 made of polyethylene. The carrier means 1 are connected with a polyamide thread 3.

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**EXAMPLE 3.**

The active body 2 of the intrauterine device proposed by the invention is a coil 4 (FIG. 1.) consisting of an alloy including 40 parts palladium and 70 parts silver.  
5 The coil 4 is wound from a wire and surrounds the carrier means 1 made of polyethylene. The carrier means 1 are connected with a polyamide thread 3.

**EXAMPLE 4.**

The active body 2 of the intrauterine device proposed by the invention is a coil 4 (FIG. 1.) consisting of an alloy including 18 parts nickel and 82 parts gold. The coil 4 is wound from a wire and surrounds the carrier means 1 made of polyethylene. The carrier means 1 are connected with a polyamide thread 3.  
10

15

**EXAMPLE 5.**

The active body 2 is a tube 5 (FIG. 2.) made of an alloy consisting of 40 parts copper, 25 parts silver and 35 parts zinc. The tube 5 is prepared by welding from a metal sheet. The carrier means 1 made of plastic are connected  
20 with a polyamide thread 3.

**EXAMPLE 6.**

The active body 2 is made of a copper wire and a copper sheet with having surface layer including gold mixed with copper. The wires are prepared in the form of the  
25 rings 6 and 8, the sheet is closed to constitute the tubular elements 7 (FIG. 3). The carrier means 1 made of plastic are connected with a thread 3 consisting of a flexible plastic.

30

**EXAMPLE 7.**

The active body 2 is made of a wire and a sheet made of an alloy consisting of 90 parts silver and 10 parts cadmium. The wires are prepared in the form of the rings 6

-11-

and 8, the sheet is closed to constitute the tubular elements 7 (FIG. 3). The carrier means 1 made of plastic are connected with a thread 3 consisting of a flexible plastic.

5       The intrauterine contraceptive devices of the invention were investigated in conditions near to the physiological. According to the observations the effective life is more than 20 years and the contraceptive effectivenes is as high as at least 99 %. The device can be applied in a fully  
10      similar way to the known devices.

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WHAT WE CLAIM IS:

- 5            1. An intrauterine contraceptive device, comprising
  - (a) an active body made of a metallic substance of contraceptive activity,
  - (b) carrier means for supporting said active body in an intrauterine environment,
- 10            characterized in that  
said active body (2) is made of at least two metals forming a plurality of galvanic cells in said intrauterine environment.
- 15            2. The contraceptive device as set forth in claim 1,  
characterized in that  
said active body (2) consists at least partially of an alloy consisting of said at least two metals.
- 20            3. The contraceptive device as set forth in claim 1 or 2, characterized in that  
said active body (2) is made from a mixture and/or alloy including at least one metal selected from the group comprising zinc, copper, nickel, silver and cadmium, and at least one metal more noble than that selected from said group.
- 25            4. The contraceptive device as set forth in claim 3,  
characterized in that  
said more noble metal is selected from the group comprising silver, gold and palladium.
- 30            5. The contraceptive device as set forth in claim 3 or 4, characterized in that  
said mixture and/or alloy comprises zinc.
6. The contraceptive device as set forth in any precedent claim, characterized in that  
said active body (2) is made in form of a coil (4) wound around said carrier means (1).

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7. The contraceptive device as set forth in any precedent claim, characterized in that said active body (2) is made at least partially in form of a tubular element (5, 7) arranged along stems (10, 11) of 5 said carrier means (1).

8. The contraceptive device as set forth in claim 7, characterized in that said active body (2) consists of at least two tubular elements (7) surrounding said carrier means (1).

10 9. The contraceptive device as set forth in claim 8, characterized in that said active body (2) consists of two tubular elements (6) and three rings (6, 8), wherein one ring is arranged on said stems (10, 11) and two are placed on arms (12, 13) of 15 said carrier means (1).

10. An intrauterine contraceptive device, comprising  
(a) an active body made of a metallic substance of contraceptive activity and  
(b) carrier means for supporting said active body in an intrauterine environment, said carrier means being made of a plastic,  
characterized in that  
said active body (2) is made of a metallic element consisting of a metal selected from the group comprising zinc, 20 copper, cadmium, nickel and silver and at least one metal of electropositivity higher than that of the metal selected from said group, said metals forming a mixture and/or an alloy, wherein said mixture and/or alloy of said metals constitute a plurality of galvanic cells in the intrauterine environment.

30 35 11. The contraceptive device as set forth in claim 11, characterized in that said metallic element comprises said at least one metal selected from the group consisting of silver, palladium and gold.

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12. The contraceptive device as set forth in claim  
11 or 12, characterized in that  
said metal selected from said group is copper, and said me-  
tallic element is made with a further metal of electropo-  
5 sitivity lower than that of copper, said further metal be-  
ing particularly zinc.

13. The contraceptive device as set forth in any of  
claims 11 to 13, characterized in that  
said active body (2) is shaped to form a coil (4) and/or at  
10 least one tubular element (5, 7).

14. The contraceptive device as set forth in claim  
15, characterized in that  
said active body (2) includes at least one ring (6, 8) sur-  
rounding said carrier means (1).

15

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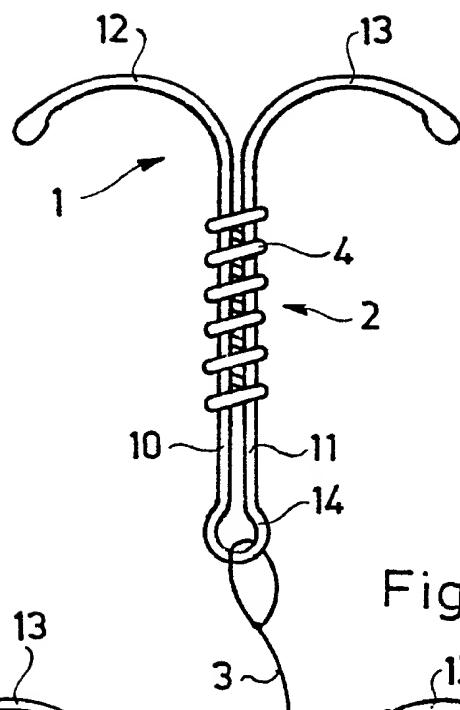


Fig. 1

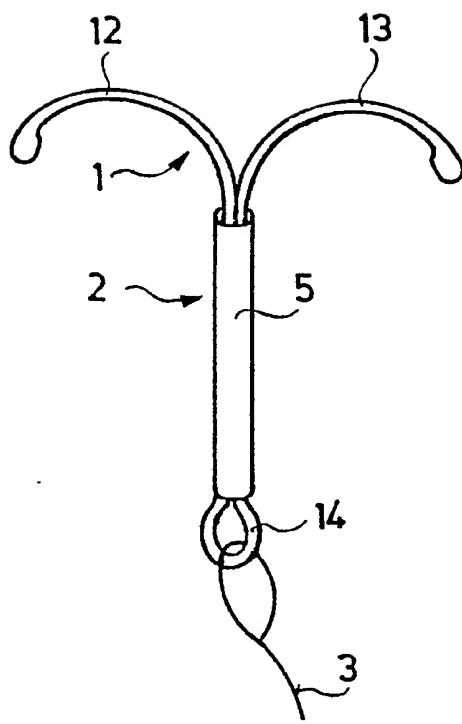


Fig. 2

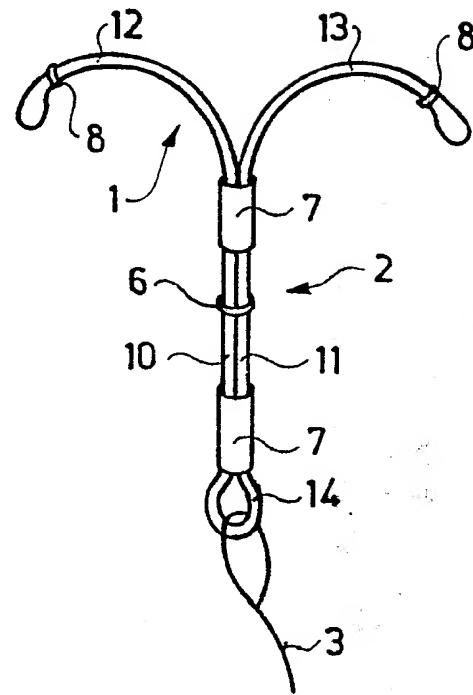


Fig. 3

# INTERNATIONAL SEARCH REPORT

International Application No PCT/HU 90/00009

## I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) <sup>6</sup>

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC<sup>5</sup>: A 61 F 6/14

## II. FIELDS SEARCHED

### Minimum Documentation Searched <sup>7</sup>

Classification System	Classification Symbols
Int.CI. <sup>5</sup> :	A 61 F 6/00, 6/06, 6/14, 6/18.
<small>Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup></small>	

## III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup>

Category <sup>10</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
A	US, A, 4 353 363 (SOPENA QUESADA) 12 October 1982 (12.10.82), see abstract; claim 1; fig. 1-3.	(1,3,6,10, 12,13)
A	US, A, 4 655 204 (BASUYAUX) 07 April 1987 (07.04.87), see column 2, line 53 - column 3, line 5; fig. 1.	(1,3,6,10, 12,13)
A	DE, A1, 2 758 037 (HERTEN KURT) 28 June 1979 (28.06.79), see page 9, line 2 - page 10, line 17; fig.	(1,3,7,10, 12,13)
A	US, A, 4 351 326 (KOSONEN) 28 September 1982 (28.09.82), see column 1, lines 41-61.	(1-4,6,10, 13)
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\* Special categories of cited documents: <sup>14</sup>

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

## IV. CERTIFICATION

Date of the Actual Completion of the International Search

29 March 1990 (29.03.90)

Date of Mailing of this International Search Report

03 April 1990 (03.04.90)

International Searching Authority

AUSTRIAN PATENT OFFICE

Signature of Authorized Officer

Anhang zum internatio-  
nalen Recherchenbericht  
über die internationale  
Patentanmeldung  
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Annex to the International  
Search Report on Interna-  
tional Patent Application  
No. PCT/HU 90/00009

This Annex lists the patent  
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Publication  
date  
Date de  
publication

US-A - 4353363	12-10-82	CH-A - 636002 DE-A1- 2925993 DE-C2- 2925993 ES-U - 239677 ES-Y - 239677	13-05-83 04-06-80 10-04-86 01-02-79 16-06-79
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US-A - 4355204	07-04-87	None
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28-09-82

YU-A	-	259/83	31-12-83
YU-A	-	857/81	31-12-83
YU-B	-	43538	31-08-89
AT-A	-	1483/81	15-02-89
AT-B	-	388865	11-09-89
BE-A1	-	888093	16-07-81
DE-A1	-	3112944	01-04-82
DE-CQ	-	3112944	09-03-89
DK-B	-	151287	23-11-87
DK-C	-	151287	04-07-88
FR-B1	-	2479685	31-01-86
GB-A1	-	2077338	16-12-81
GB-B2	-	2077338	14-03-84
IT-A	-	1170858	03-09-87
JP-A2-56156152	-		02-12-81
LU-A	-	83274	11-09-81
NO-A	-	811117	24-11-81
NO-B	-	151393	27-12-84
NO-C	-	151393	03-04-85
NZ-A	-	196467	31-05-84
PT-A	-	72658	01-04-81
PT-B	-	72658	01-04-81
PT-B	-	72658	19-03-82
SE-B	-	449297	27-04-87
SE-C	-	449297	06-09-87
YU-B	-	41776	31-12-87
ZA-A	-	8101950	28-04-82